

AMENDED IN ASSEMBLY APRIL 5, 2010

CALIFORNIA LEGISLATURE—2009–10 REGULAR SESSION

ASSEMBLY BILL

No. 1709

Introduced by Assembly Member Conway

February 2, 2010

~~An act to amend Section 9211 of the Food and Agricultural Code,~~
An act to amend Sections 9203, 9211, 9212, 9221, 9231, 9241, 9242, 9244, 9245, 9251, 9261, 9263, 9264, 9267, and 9268 of, to amend the heading of Chapter 1.5 (commencing with Section 9201) of Part 1 of Division 5 of, to amend the heading of Article 5 (commencing with Section 9241) of Chapter 1.5 of Part 1 of Division 5 of, to add Section 9210 to, to add the heading of Article 2 (commencing with Section 9210) to Chapter 1.5 of Part 1 of Division 5 of, to add, amend, and renumber Section 9204 of, to repeal Section 9243 of, to repeal the heading of Article 2 (commencing with Section 9211) of Chapter 1.5 of Part 1 of Division 5 of, and to repeal and add Section 9205 of, the Food and Agricultural Code, relating to biologics.

LEGISLATIVE COUNSEL'S DIGEST

AB 1709, as amended, Conway. ~~Biologics.~~ *Biologics: animal blood and blood component products: commercial blood banks for animals.*

Existing law defines biologics, requires the Secretary of Food and Agriculture to license biologic establishments that meet specified requirements, provides requirements relating to the application for a biologic license, and requires a certain biologic license application fee and license renewal fee. A violation of these provisions is a crime.

This bill would revise the definition of biologics, prohibit a person from engaging in the production of animal blood and blood component products, as defined, for retail sale and distribution except in a

commercial blood bank for animals, as defined, licensed by the secretary, delete the requirement that the secretary license biologic establishments and instead require the secretary to license commercial blood banks for animals that meet specified requirements, and revise the license application provisions and license application fee and renewal fee provisions to instead make them applicable to producers of animal blood and blood component products. Because this bill would change the definition of an existing crime and create new crimes, the bill would impose a state-mandated local program.

Existing law prohibits a person from engaging in the production of biologics except in an establishment licensed by the United States Department of Agriculture or the Secretary of Food and Agriculture or in an establishment producing biologics only for use by the owner or operator for animals owned by him or her.

~~This bill would make technical, nonsubstantive changes to those provisions~~ *instead prohibit a person from engaging in the production of biologics except as permitted under federal law.*

Existing law prohibits the offer for sale or use of any biologic unless it is registered by the secretary, except that registration is not required of any biologic manufactured pursuant to the terms of a valid license issued by the United States Department of Agriculture unless the secretary finds that, due to local conditions, it is necessary that the biologic be registered.

This bill would, instead, prohibit the offer for sale or use of any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the United States Department of Agriculture. The bill would also prohibit the offer for sale or use of any blood or blood component product unless it is produced in an establishment licensed by the secretary, thereby imposing a state-mandated local program by creating a new crime.

Existing law requires the secretary to register any biologic that meets certain requirements and a biologic that is produced in an establishment exempt from licensing and that meets certain requirements, provides requirements relating to the application for registration of a biologic, and authorizes the secretary to impose conditions on the production or use of biologics.

This bill would delete the requirement that the secretary register biologics and instead require the secretary to register blood or blood component products that meet certain requirements. The bill would also require an application for registration of blood or blood component

products to include specified information and would authorize the secretary to impose conditions on the production or use of blood or blood component products.

Existing law provides various enforcement provisions that the secretary may undertake with respect to biologic licensees and registrants.

This bill would revise those enforcement provisions to instead make them applicable to commercial blood banks for animals licensees and registrants of blood or blood component products.

This bill would make other conforming, clarifying, and technical changes.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

The people of the State of California do enact as follows:

1 SECTION 1. The heading of Chapter 1.5 (commencing with
2 Section 9201) of Part 1 of Division 5 of the Food and Agricultural
3 Code is amended to read:

4
5 CHAPTER 1.5. COMMERCIAL BLOOD BANKS FOR ANIMALS AND
6 BIOLOGICS
7

8 SEC. 2. Section 9203 of the Food and Agricultural Code is
9 amended to read:

10 9203. “Biologics” means ~~the following products which are~~
11 ~~used for the diagnosis and detection of, and for the prevention or~~
12 ~~treatment of, disease in animals other than man: serum, blood,~~
13 ~~vaccines, live vaccine, killed vaccine, tissue vaccine, autogenous~~
14 ~~vaccine, live virus, killed virus, live bacterial culture, killed~~
15 ~~bacterial culture, bacterin, hormone, tissue extract, gland extract,~~
16 ~~gland preparation, insulin, and similar products made from human~~
17 ~~or animal tissues or micro-organisms all viruses, serums, antibody~~
18 ~~products, toxins (excluding substances that are selectively toxic~~

1 to microorganisms, for example, antibiotics), or analogous
2 products at any stage of production, shipment, distribution, or
3 sale, which are intended for use in the treatment of animals and
4 which act primarily through the direct stimulation,
5 supplementation, enhancement, or modulation of the immune
6 system or immune response.

7 SEC. 3. Section 9204 is added to the Food and Agricultural
8 Code, to read:

9 9204. “Blood and blood component products” means whole
10 blood collected directly from a donor animal for transfusion or
11 the blood components for transfusion including packed red blood
12 cells, platelet-rich plasma, platelet concentrates, fresh plasma,
13 fresh frozen plasma, frozen plasma, cryoprecipitate, and
14 cryosupernatant. Antibody products like hyperimmune serums are
15 considered “biologics” and are excluded from this definition of
16 blood and blood component products.

17 SEC. 4. Section 9204 of the Food and Agricultural Code is
18 amended and renumbered to read:

19 ~~9204.~~

20 9206. “Production” means collection of ~~biologic material;~~
21 blood or the preparation, testing, processing, storage, or distribution
22 of ~~biologies~~ blood or blood component products for the purpose
23 of transfusion.

24 SEC. 5. Section 9205 of the Food and Agricultural Code is
25 repealed.

26 ~~9205. “Serial” means the total quantity of a biological product~~
27 ~~in final composition which has been mixed in a single container~~
28 ~~and identified by number.~~

29 SEC. 6. Section 9205 is added to the Food and Agricultural
30 Code, to read:

31 9205. “Commercial blood bank for animals” means an
32 establishment that produces animal blood or blood component
33 products to market and sell for use in the cure, mitigation,
34 treatment, or prevention of disease in animals.

35 SEC. 7. The heading of Article 2 (commencing with Section
36 9211) of Chapter 1.5 of Part 1 of Division 5 of the Food and
37 Agricultural Code is repealed.

38
39 ~~Article 2. Biologies Production~~
40

1 *SEC. 8. The heading of Article 2 (commencing with Section*
2 *9210) is added to Chapter 1.5 of Part 1 of Division 5 of the Food*
3 *and Agricultural Code, to read:*

4
5 *Article 2. Animal Blood and Blood Component Products*
6 *Production and Biologics Production*
7

8 *SEC. 9. Section 9210 is added to the Food and Agricultural*
9 *Code, to read:*

10 *9210. No person shall engage in the production of animal*
11 *blood and blood component products for retail sale and*
12 *distribution except in a commercial blood bank for animals*
13 *licensed by the secretary.*

14 *SEC. 10. Section 9211 of the Food and Agricultural Code is*
15 *amended to read:*

16 *9211. No person shall engage in the production of biologics*
17 *except in any of the following: as permitted under federal law.*

18 ~~(a) In an establishment licensed by the United States Department~~
19 ~~of Agriculture.~~

20 ~~(b) In an establishment producing biologics only for use by the~~
21 ~~owner or operator of that establishment for animals owned by him~~
22 ~~or her. Biologics produced in such an establishment shall be~~
23 ~~registered by the director under this chapter.~~

24 ~~(c) In an establishment licensed by the director.~~

25 *SEC. 11. Section 9212 of the Food and Agricultural Code is*
26 *amended to read:*

27 *9212. The secretary shall license biologic establishments as*
28 *commercial blood banks for animals that meet all of the following:*

29 (a) Operate under conditions, and use methods of production,
30 ~~to insure~~ *ensure* that the ~~biologics animal blood and blood~~
31 ~~component products~~ will not be contaminated, dangerous, or
32 harmful.

33 (b) Produce ~~biologics animal blood and blood component~~
34 ~~products~~ under the direct supervision of a person qualified in the
35 ~~field of production of biologics.~~

36 ~~(c) For those commercial blood banks for animals licensed by~~
37 ~~the department, maintain~~ *Maintain* onsite records containing
38 information documenting how the animal was acquired and any
39 history of blood draws or use of anesthesia on the animal.

1 *SEC. 12. Section 9221 of the Food and Agricultural Code is*
2 *amended to read:*

3 9221. An application for a license for any establishment that
4 produces, or proposes to produce, ~~biologies animal blood and~~
5 ~~blood component products~~ shall be made on forms to be issued by
6 the secretary. The application shall contain all of the following:

7 (a) The name and address of the person who owns the place,
8 establishment, or institution in which it is proposed to produce
9 ~~biologies animal blood and blood component products.~~

10 (b) The name and address of the person who shall be in charge
11 of ~~biologies the production of animal blood and blood component~~
12 ~~products.~~

13 (c) The type of ~~biologies animal blood and blood component~~
14 ~~products~~ that shall be produced.

15 (d) A full description of the building, including its location,
16 facilities, equipment, and apparatus to be used in ~~biologies the~~
17 ~~production of animal blood and blood component products.~~

18 (e) A written protocol ~~for a commercial blood bank for animals~~
19 that addresses all of the following:

20 (1) Maximum length of time for donation by animal donors, or
21 minimum health parameters for animal donors.

22 (2) Frequency and volume of blood collected from animal blood
23 donors.

24 (3) Socialization and exercise programs for animal blood donors.

25 (4) Method of identification of each animal, including microchip
26 or tattoo.

27 (5) Ongoing veterinary care, including an annual physical exam
28 and vaccination schedule for animals held in blood donor facilities.

29 (6) Husbandry standards for feeding, watering, sanitation,
30 housing, handling, and care in transit, with minimums based on
31 the standards set forth pursuant to the federal Animal Welfare Act
32 in Part 3 (commencing with Section 3.1) of Subchapter A of
33 Chapter 1 of Title 9 of the Code of Federal Regulations.

34 (7) Implementation of a permissive adoption program.

35 (f) An “oversight letter” identifying the oversight veterinarian
36 who will be responsible for oversight of the facility. The letter
37 shall be from the oversight veterinarian, and shall be maintained
38 on file by the secretary. Oversight veterinarians shall be licensed
39 to practice veterinary medicine in California. In the event of a
40 change of the oversight veterinarian, it is the oversight

1 veterinarian's responsibility to give notice to the secretary of the
2 termination of the oversight veterinarian within 30 days of the
3 termination date of the oversight veterinarian. An oversight letter
4 from the incoming oversight veterinarian shall be submitted to the
5 secretary within 30 days of the termination date of the prior
6 oversight veterinarian.

7 (g) Additional information that the secretary finds is necessary
8 for the proper administration and enforcement of this chapter.

9 *SEC. 13. Section 9231 of the Food and Agricultural Code is*
10 *amended to read:*

11 9231. The license application fee and license renewal fee under
12 this chapter for an establishment proposing to produce or producing
13 ~~biologies~~ animal blood and blood component products shall be as
14 follows:

15 (a) The application and annual license fee shall be two hundred
16 fifty dollars (\$250) for each establishment, which shall be the fee
17 for the fiscal year, or portion thereof, ending June 30 of each year.
18 When an applicant is a city, county, state, or district, or an official
19 thereof, no fee shall be required under this section.

20 (b) Licenses shall be renewed every year. The annual renewal
21 fee shall be paid on or before the first day of July of each year.

22 (c) ~~For commercial blood banks for animals licensed by the~~
23 ~~department, fees~~ Fees may be increased by the department to cover
24 the department's reasonable costs incurred in connection with
25 performing the annual inspection required by Sections 9266 and
26 9268.

27 (d) The fees required by this section are maximum, and may be
28 fixed by the secretary at a lesser amount for any fiscal year
29 whenever he or she finds that the cost of administering this chapter
30 can be defrayed from revenues derived from the lower fees.

31 *SEC. 14. The heading of Article 5 (commencing with Section*
32 *9241) of Chapter 1.5 of Part 1 of Division 5 of the Food and*
33 *Agricultural Code is amended to read:*

34
35 Article 5. ~~Biologic~~Blood or Blood Component Product
36 Registration
37

38 *SEC. 15. Section 9241 of the Food and Agricultural Code is*
39 *amended to read:*

40 9241. No person shall offer for sale or use any of the following:

1 ~~(a) Any biologic unless it is registered by the director pursuant~~
2 ~~to this article, except, however, no such registration shall be~~
3 ~~required of any biologic manufactured pursuant to the terms of a~~
4 ~~valid license or permit issued by the United States Department of~~
5 ~~Agriculture unless the director finds that, due to local conditions,~~
6 ~~it is necessary that the biologic be registered in order to assure that~~
7 ~~it have value for the purpose intended and it is safe to use in this~~
8 ~~state.~~

9 ~~(b) Any blood or blood component product unless it is produced~~
10 ~~in an establishment licensed by the secretary.~~

11 ~~SEC. 16. Section 9242 of the Food and Agricultural Code is~~
12 ~~amended to read:~~

13 ~~9242. The director secretary shall register any biologic blood~~
14 ~~or a blood component product that meets all of the following~~
15 ~~requirements:~~

16 ~~(a) It is produced under acceptable procedures, which include~~
17 ~~tests to insure its purity and safety.~~

18 ~~(b) The production and use of such type of biologic has not been~~
19 ~~specifically forbidden or disapproved by the director, the United~~
20 ~~States Department of Agriculture, or the United States Public~~
21 ~~Health Service.~~

22 ~~(c)~~
23 ~~(b) It has been demonstrated to the director secretary that such~~
24 ~~a biologic the blood or blood component product is safe and~~
25 ~~noninjurious to human or animal health.~~

26 ~~(d)~~
27 ~~(c) It has been demonstrated to the director secretary that such~~
28 ~~a biologic the blood or blood component product is of value for~~
29 ~~the purpose intended.~~

30 ~~(e)~~
31 ~~(d) It is labeled for proper handling and use, and is not~~
32 ~~misrepresented.~~

33 ~~(f)~~
34 ~~(e) It is produced in an establishment that meets the requirements~~
35 ~~of subdivision (a) or (c) of Section 9211 9210.~~

36 ~~SEC. 17. Section 9243 of the Food and Agricultural Code is~~
37 ~~repealed.~~

38 ~~9243. The director shall register a biologic, if it is produced in~~
39 ~~an establishment exempt from licensing pursuant to subdivision~~

1 ~~(b) of Section 9211 and meets the requirements of subdivisions~~
2 ~~(a), (b), and (c) of Section 9242.~~

3 *SEC. 18. Section 9244 of the Food and Agricultural Code is*
4 *amended to read:*

5 9244. An application for registration of a ~~biologic blood or a~~
6 ~~blood component product~~ shall include both of the following:

7 (a) A protocol of ~~the~~ methods of production in detail ~~which that~~
8 is followed in the production of the product.

9 (b) A sample of the label to be placed on the ~~biologic blood or~~
10 ~~blood component product.~~

11 *SEC. 19. Section 9245 of the Food and Agricultural Code is*
12 *amended to read:*

13 9245. The ~~director~~ *secretary* may impose such conditions on
14 the production or use of ~~biologies blood or blood component~~
15 ~~products~~ as he or she deems necessary to accomplish the purposes
16 of this chapter.

17 *SEC. 20. Section 9251 of the Food and Agricultural Code is*
18 *amended to read:*

19 9251. The ~~director~~ *secretary* may adopt reasonably necessary
20 rules and regulations for the administration and enforcement of
21 this chapter.

22 *SEC. 21. Section 9261 of the Food and Agricultural Code is*
23 *amended to read:*

24 9261. License for any ~~establishment commercial blood bank~~
25 ~~for animals~~ or registration of any ~~biologic blood or blood~~
26 ~~component product~~ may be denied, suspended, or revoked by the
27 ~~director~~ *secretary* for failure to meet the requirements of this
28 chapter or for the violation of any provision of this chapter, or of
29 any rule or regulation adopted by the ~~director~~ *secretary* under this
30 chapter. The proceedings shall be conducted in accordance with
31 Chapter 5 (commencing with Section 11500); of Part 1; of Division
32 3; of Title 2 of the Government Code.

33 *SEC. 22. Section 9263 of the Food and Agricultural Code is*
34 *amended to read:*

35 9263. If the ~~director~~ *secretary* finds that ~~biologies blood or~~
36 ~~blood component products~~ do not conform to the requirements of
37 Section 9242 or 9243 or the use or continued use of such products
38 constitutes an immediate danger to ~~persons or animals,~~ *he the*
39 *secretary* may, after notice, suspend the registration of ~~such~~
40 ~~biologies those blood or blood component products~~ or license of

1 an establishment producing ~~such biologies~~ *those blood or blood*
2 *component products* pending a hearing and final decision.

3 *SEC. 23. Section 9264 of the Food and Agricultural Code is*
4 *amended to read:*

5 9264. (a) If the ~~director~~ *secretary* finds a ~~serial or serials of a~~
6 ~~registered biologic which~~ *blood or blood component products that*
7 do not meet the requirements of Section 9242 ~~or 9243~~, ~~he the~~
8 *secretary* may order ~~such serial or serials~~ *those blood or blood*
9 *component products* to be held on the premises where found or
10 elsewhere until he *or she* has determined that the products may be
11 safely released for the purposes intended.

12 ~~The director~~

13 (b) *The secretary* may order the destruction of any *blood or*
14 *blood component products* under ~~such a~~ hold order if the *blood or*
15 *blood component products* cannot be made to meet the
16 requirements of Section 9242 ~~or 9243~~.

17 *SEC. 24. Section 9267 of the Food and Agricultural Code is*
18 *amended to read:*

19 9267. Notwithstanding Section 4827 of the Business and
20 Professions Code, for commercial blood banks for animals licensed
21 by the department, anesthesia shall be performed ~~by a California~~
22 ~~licensed veterinarian or by a registered veterinary technician under~~
23 ~~the direct supervision of a California licensed veterinarian pursuant~~
24 ~~to Section 4826 of the Business and Professions Code.~~

25 *SEC. 25. Section 9268 of the Food and Agricultural Code is*
26 *amended to read:*

27 9268. The requirements set forth in subdivision (c) of Section
28 9212, subdivision (e) of Section 9221, subdivision (c) of Section
29 9231, and Sections ~~9265~~, 9266, and 9267:

30 (a) Shall not apply to those facilities required to be inspected
31 by the United States Department of Agriculture in accordance with
32 the Animal Welfare Act (Chapter 54 (commencing with Section
33 2131) of Title 7 of the United States Code), ~~or to federal biologies~~
34 ~~licensees~~.

35 (b) Shall apply to those facilities housing blood donor animals
36 under contract with commercial blood banks for animals licensed
37 by the department.

38 (c) Shall not apply to private veterinarians who maintain their
39 own, in-office blood donor animals for use in their own practice.

1 *SEC. 26. No reimbursement is required by this act pursuant*
2 *to Section 6 of Article XIII B of the California Constitution because*
3 *the only costs that may be incurred by a local agency or school*
4 *district will be incurred because this act creates a new crime or*
5 *infraction, eliminates a crime or infraction, or changes the penalty*
6 *for a crime or infraction, within the meaning of Section 17556 of*
7 *the Government Code, or changes the definition of a crime within*
8 *the meaning of Section 6 of Article XIII B of the California*
9 *Constitution.*

10 ~~SECTION 1. Section 9211 of the Food and Agricultural Code~~
11 ~~is amended to read:~~

12 ~~9211. No person shall engage in the production of biologics~~
13 ~~except in any of the following:~~

14 ~~(a) In an establishment licensed by the United States Department~~
15 ~~of Agriculture.~~

16 ~~(b) In an establishment producing biologics only for use by the~~
17 ~~owner or operator of that establishment for animals owned by him~~
18 ~~or her. Biologics produced in such an establishment shall be~~
19 ~~registered by the secretary under this chapter.~~

20 ~~(c) In an establishment licensed by the secretary.~~